

**Emergency Exemption for Transform® WG Insecticide (sulfoxaflor) to control the newly introduced sugarcane aphid, *Melanaphis sp.* in sorghum.**

**Type of Exemption** - Arkansas Section 18; Specific Exemption Request; January 18, 2016.

This is an application for a specific exemption to authorize the use of Sulfoxaflor (Transform® WG Insecticide EPA Reg. No. 62719-625) to control the newly introduced sugarcane aphid (SA), *Melanaphis sp.* in sorghum. The following information is submitted in the format indicated in the proposed rules for Chapter 1, Title 40 CFR, Part 166.

**SECTION 166.20(a)(1): IDENTITY OF CONTACT PERSONS**

- i. The following are the contact persons responsible for the administration of the emergency exemption:

**Mr. Terry Walker**

Director  
Arkansas State Plant Board  
P.O. Box 1069  
Little Rock, AR 72203  
501-225-1598  
[darryl.little@aspb.ar.gov](mailto:darryl.little@aspb.ar.gov)

**Ms. Brandi Reynolds**

Assistant Director- Product Registration for Pesticide Division  
Arkansas State Plant Board  
P.O. Box 1069  
Little Rock, AR 72203  
501-225-1598  
[brandi.reynolds@aspb.ar.gov](mailto:brandi.reynolds@aspb.ar.gov)

- ii. The following qualified experts are also available to answer questions:

**Gus Lorenz**

Distinguished Professor, Extension Entomologist  
Entomology  
University of AR, Division of Agriculture  
2001 Highway 70 East, Lonoke, AR 72086  
Tel: 501-438-6088  
E-mail: [glorenz@uaex.edu](mailto:glorenz@uaex.edu)

Glenn Studebaker  
Associate Professor, Extension Entomologist  
Entomology  
University of AR, Division of Ag  
NE Research and Extension Center  
Box 48 NEREC, Keiser, AR 72351  
Tel: 870-526-2199  
E-mail: [gstudebaker@uaex.edu](mailto:gstudebaker@uaex.edu)

Nick Seiter  
Asst. Professor  
University of AR, Division of Ag  
Southeast Research and Extension Center  
P.O. Box 3508, Monticello, AR 71656  
Tel: 870-460-1091  
E-mail: [nseiter@uaex.edu](mailto:nseiter@uaex.edu)

Jason Kelley  
Extension Agronomist- Feed Grains  
University of AR, Division of Ag  
U of A CES, 2201 Brookwood Dr., Little Rock, AR  
Tel: 501-671-2000  
E-mail: [jkelley@uaex.edu](mailto:jkelley@uaex.edu)

Registrant Representative  
**Tami Jones-Jefferson**  
U.S. Regulatory Leader  
U.S. Regulatory & Government Affairs – Crop Protection  
Dow AgroSciences  
9330 Zionsville Road  
Indianapolis IN, 46268  
Tel: 317.337.3574  
Email: [tjjonesjefferson@dow.com](mailto:tjjonesjefferson@dow.com)

**Jamey Thomas**  
US Regulatory Manager  
Dow AgroSciences  
9330 Zionsville Road  
Indianapolis, IN. 46268

## SECTION 166.20(a)(2): DESCRIPTION OF THE PESTICIDE REQUESTED

i. **Common Chemical Name (Active Ingredient):** Sulfoxaflor

Brand/Trade Name and EPA Reg. No.: Transform® WG Insecticide,  
EPA Reg. No. 62719-625 (Attachment 1)  
Formulation: Active Ingredient 50%

## SECTION 166.20(a)(3): DESCRIPTION OF THE PROPOSED USE

i. **Sites to be treated:**

Sorghum fields (grain and forage) with the newly introduced sugarcane aphid (SA), *Melanaphis sp.* located statewide are proposed to be treated.

ii. **Method of Application:**

The proposed method of application will be a foliar application when large SA populations are present, causing leaf discoloration and damaging leaves.

iii. **Rate of Application:**

The proposed rate of application is 0.75 – 1.5 oz of Transform® WG/acre (0.023 – 0.047 lb ai/acre).

iv. **Maximum Number of Applications:**

The proposed maximum number of applications is three applications per year (maximum of 3 oz/acre (0.094 lb ai/acre))

v. **Total Acreage to be Treated:**

Based on information provided by Dr. Jason Kelley, Professor, Feed Grains Specialist in the UA Div. of Ag, approximately 500,000 acres of sorghum were planted in Arkansas in 2015. Due to the reduced commodity price for grain sorghum in 2016, Dr. Kelley estimates acreage will go down to approximately 250,000 acres.

vi. **Total Amount of Pesticide to be used:**

We estimate the SCA was present on 100% of grain sorghum acres grown in Arkansas in 2015, with the increased range of the SCA into Arkansas, Missouri and Kentucky. In 2014 southern counties experienced worst infestations, however, in 2015 we observed that the worst infestations were in the northern one-half of the state. This was due to SCA expanding its range coupled with late planting in the northeast due to spring rains in that part of the state. The attached map shows distribution of sugarcane aphid across Arkansas and the southern U.S. (Attachment 2). Since the aphids were found in west Tennessee, through the bootheel of Missouri and up into Kentucky and Kansas to the west we must conclude that all grain sorghum producing counties in the state will have

the potential for infestation in 2016. Most of the grain sorghum acreage is grown in the northern one-half of the state.

Therefore, if an estimated maximum SA infestation (100% infestation on 250,000 acres of sorghum) were treated at the maximum rate (1.5 oz/acre or 0.047 lb ai/acre) with the maximum number of applications (2 applications or 3.0 oz/acre or 0.094 lb ai/acre), then 46,875 lbs of Transform® WG or 23,500 pounds of active ingredient would be used in 2016.

**vii. Restrictions and Requirements:**

Refer to the Transform® WG container label for first aid, precautionary statements, directions for use and conditions of sale and warranty information. It is a violation of federal law to use this product in a manner that is inconsistent with all applicable label directions, restrictions and precautions found in the container label and this supplemental label. Both the container label and this supplemental section 18 quarantine exemption label must be in the possession of the user at the time of application.

- Applicable restrictions and requirements concerning the proposed use and the qualifications of applicators using Transform® WG are as follows:
- Pre-harvest Interval: Do not apply within 14 days of harvest for grain or 7 days of harvest for forage or stover.
- A restricted entry interval (REI) of 24 hours must be observed.
- Minimum Treatment Interval: Do not make applications less than 14 days apart.
- Do not make more than two applications per acre per year.
- Do not apply more than a total of 3.0 oz of Transform WG (0.09 lb ai of sulfoxaflor) per acre per year.

**viii. Duration of the Proposed Use:**

The duration of the proposed use would extend from spring (May15) through late summer (October 31).

**ix. Earliest Possible Harvest Date:**

Based on USDA/NASS statistics (Attachment 3), in Arkansas sorghum planting dates range, on average, from April 1 – May 15. Arkansas harvest dates, on average, range from August 1 – September 15. The usual beginning harvest date is August15.

**SECTION 166.20(a)(4): ALTERNATIVE METHODS OF CONTROL**

**i. Registered Alternative Pesticides:**

The active ingredients - imidacloprid, clothianidin, thiamethoxam, and terbufos are registered only as seed treatments and in-furrow applications. Currently we have no data that suggests anything other than short term control (30 days post planting) of SA

in early season scenarios. Additionally, virtually all sorghum seed planted in Arkansas contains one of these seed treatments. Data generated in Louisiana in 2013 studies suggest that these products do not offer season long protection, our studies on seed treatments concur with these findings. Other products tested in Arkansas and the Mid-south since 2013, including chlorpyrifos, dimethoate, and malathion provided only 20-50% control of SA in sorghum. Our data on SA in 2014 and 2015 indicate that pyrethroids aggravate or flare SCA infestations. Also, the PHI (pre harvest interval) for products containing chlorpyrifos and dimethoate range from 28-60 days, thus preventing their legal use when late season infestations occurred in 2014 and 2015. For the 2016 growing season, Sivanto® (labeled for use in 2015) will likely be available to producers for SCA control. However, it is critical that growers be able to rotate classes of insecticides to avoid loss of control and resistance issues.

**ii. Alternative Practices:**

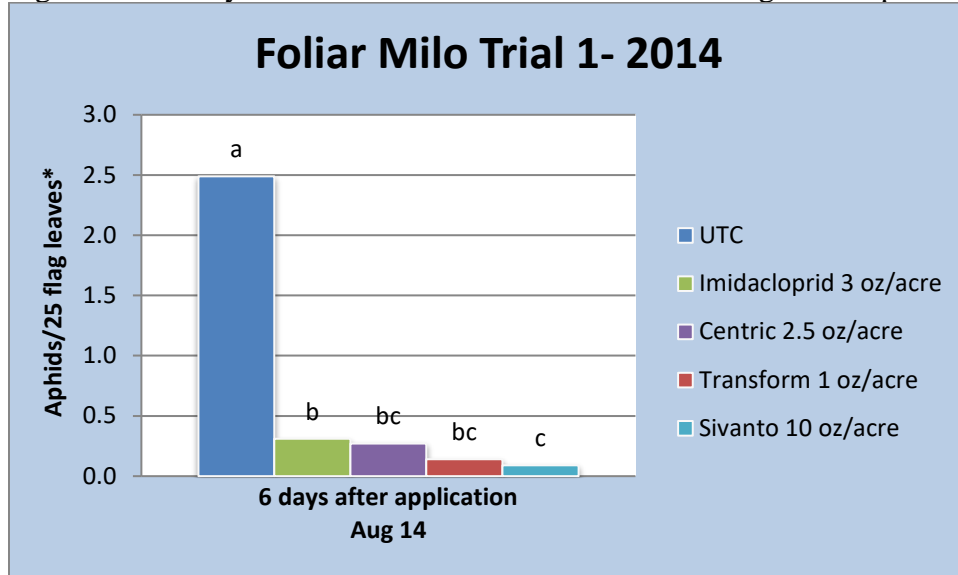
Aphid resistant varieties of sorghum have been identified by researchers, but sufficient quantities of agronomically acceptable cultivars will not be available for the 2016 planting season. Also, other alternative/cultural methods of control, such as, destruction of over-wintering insect habitat and releases of beneficial insects during the season are either not logistically feasible and/or have not been studied to demonstrate effectiveness.

**SECTION 166.20(a)(5): EFFECTIVENESS OF USE PROPOSED UNDER SECTION**

Several trials have been conducted in Arkansas in 2014 and 2015 growing seasons. These trials confirm that sulfoxaflor provides excellent control compared to currently labeled products such as dimethoate and Lorsban and similar to that of Sivanto, for controlling *Melanaphis sacchari* in grain sorghum. Observations of grower fields indicated that applications of sulfoxaflor were very effective for control while other products such as dimethoate and Lorsban were not effective at all.

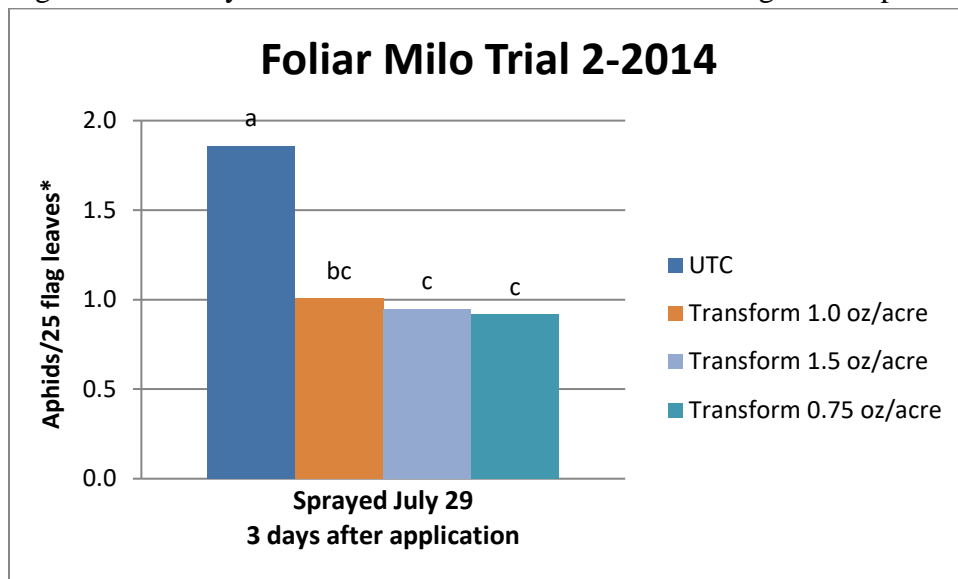
The following data is provided to show the efficacy of sulfoxaflor for control of sugarcane aphid in grain sorghum (see Figures 1 through 13). The data clearly shows the control of Transform is superior to Lorsban and Dimethoate and resulted in increasing yields by 50-60 bushels with a 70 bushel increase over the untreated check.

Figure 1. Efficacy of selected insecticides for control of sugarcane aphid.



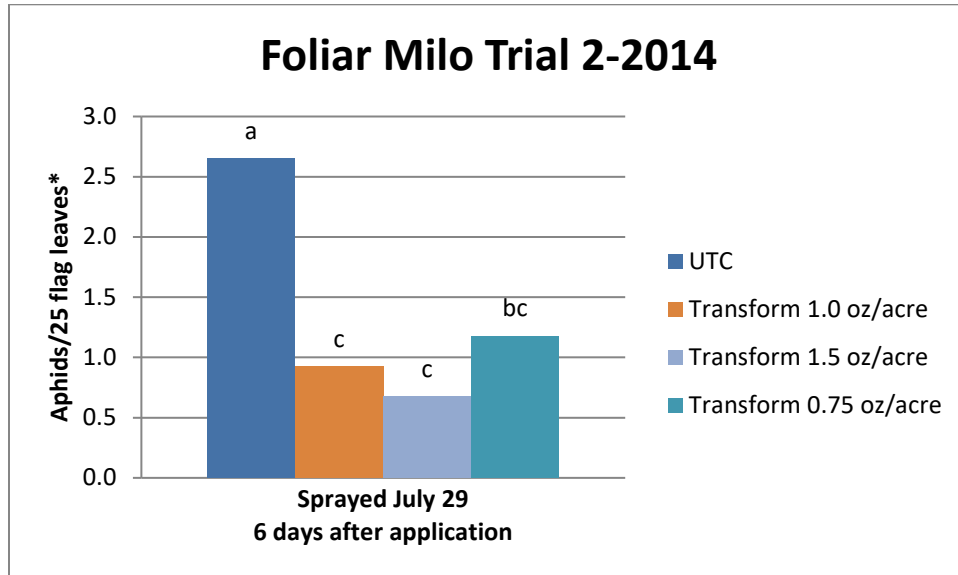
\*Rating Scale - 0=none, 1=1-100, 2=101-200' 3==300 and above.

Figure 2. Efficacy of selected insecticides for control of sugarcane aphid.



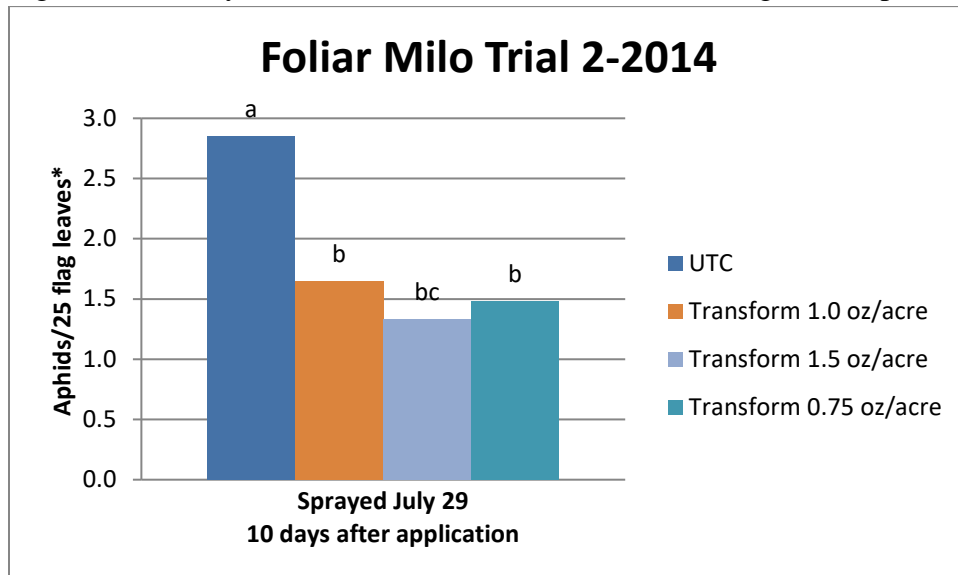
\*Rating Scale - 0=none, 1=1-100, 2=101-200' 3==300 and above.

Figure 3. Efficacy of selected insecticides for control of sugarcane aphid.



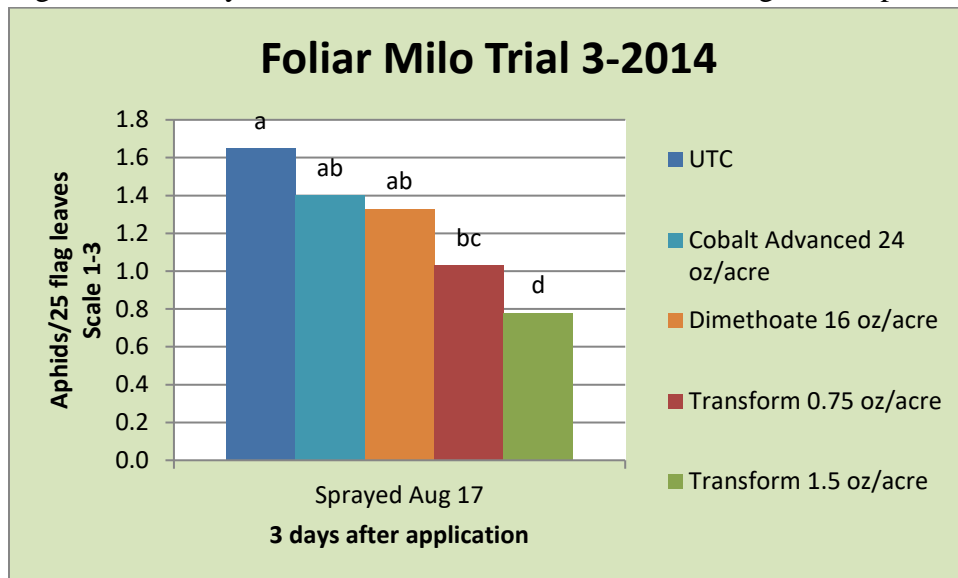
\*Rating Scale - 0=none, 1=1-100, 2=101-200' 3==300 and above.

Figure 4. Efficacy of selected insecticides for control of sugarcane aphid.



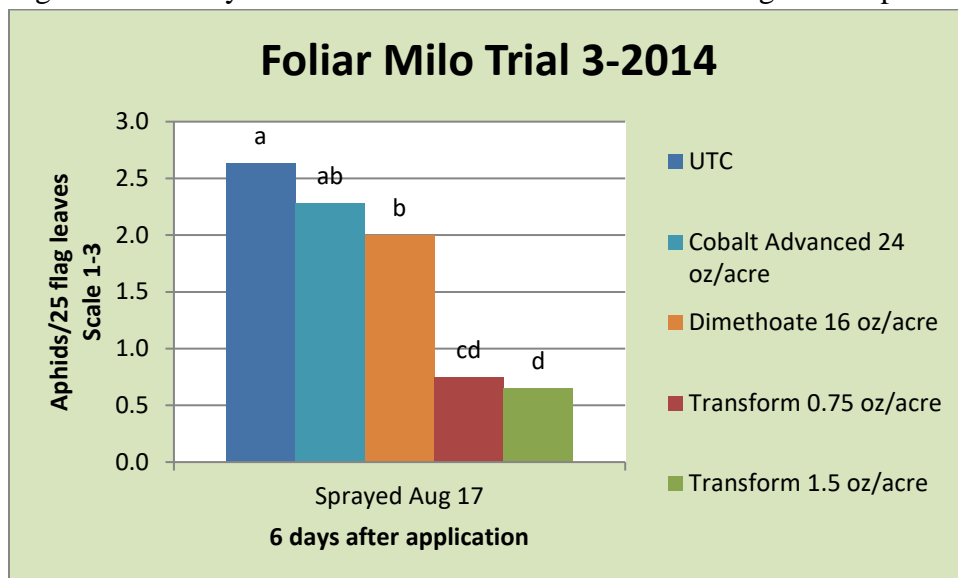
\*Rating Scale - 0=none, 1=1-100, 2=101-200' 3==300 and above.

Figure 5. Efficacy of selected insecticides for control of sugarcane aphid.



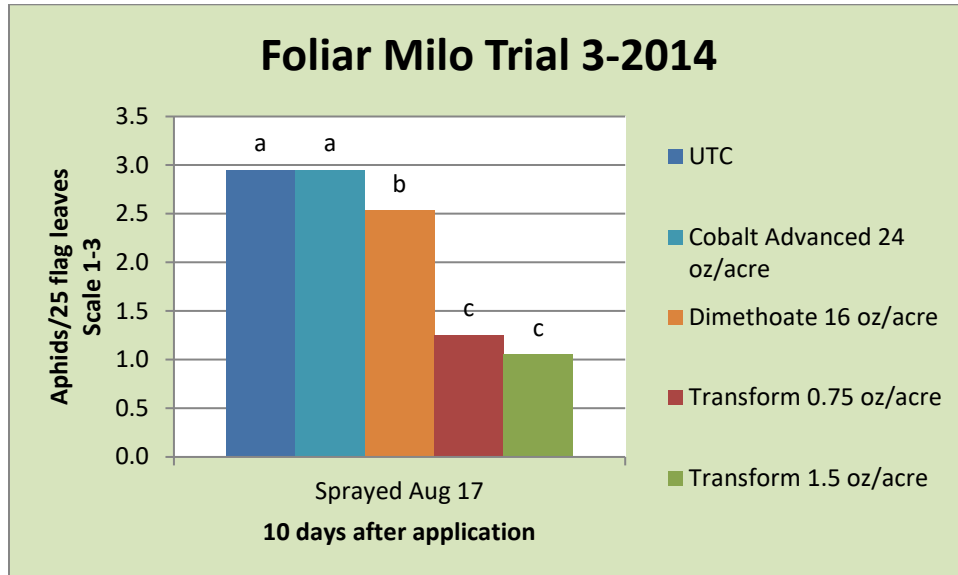
\*Rating Scale - 0=none, 1=1-100, 2=101-200' 3==300 and above.

Figure 6. Efficacy of selected insecticides for control of sugarcane aphid.



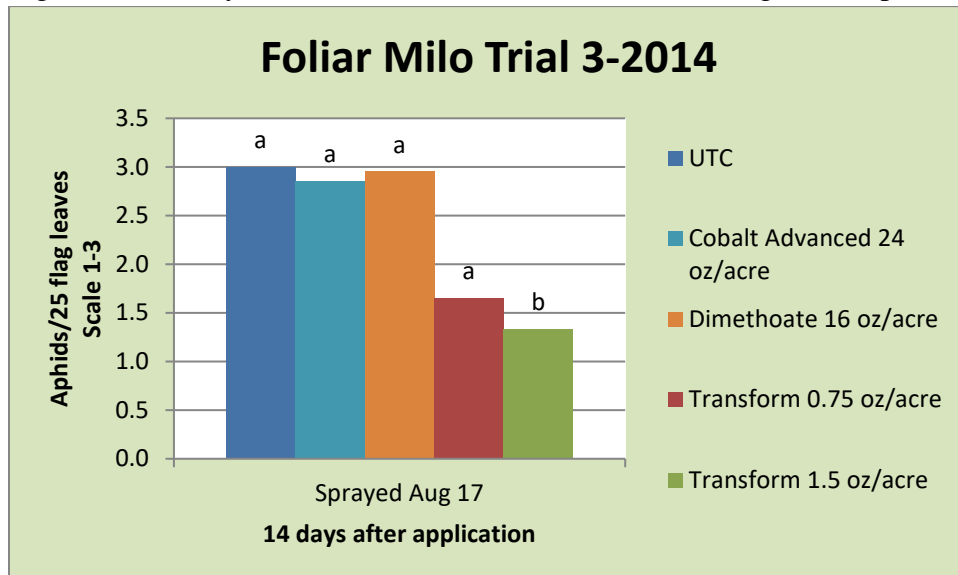
\*Rating Scale - 0=none, 1=1-100, 2=101-200' 3==300 and above.

Figure 7. Efficacy of selected insecticides for control of sugarcane aphid.



\*Rating Scale - 0=none, 1=1-100, 2=101-200' 3==300 and above.

Figure 8. Efficacy of selected insecticides for control of sugarcane aphid.



\*Rating Scale - 0=none, 1=1-100, 2=101-200' 3==300 and above.

Figure 9. Efficacy of selected insecticides for control of sugarcane aphid.

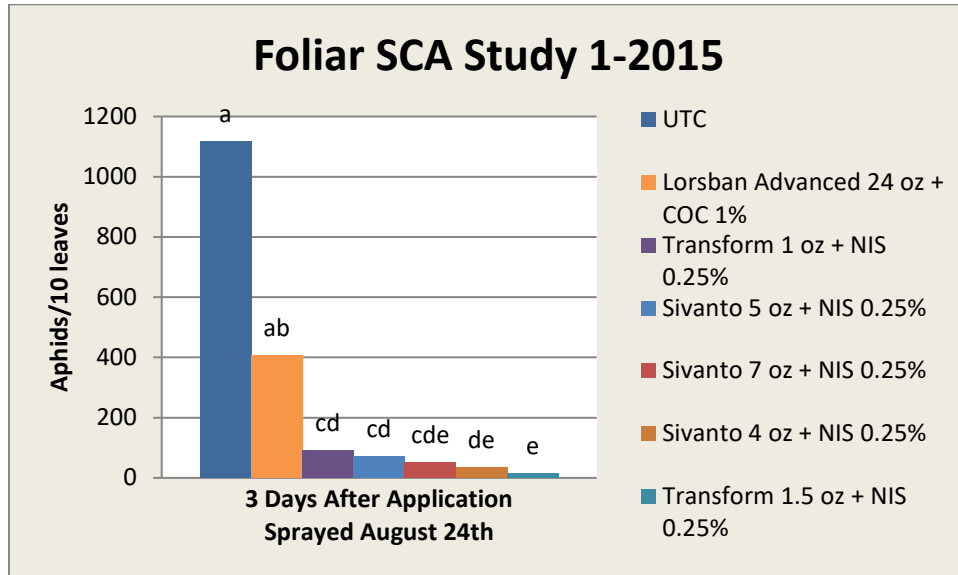


Figure 10. Efficacy of selected insecticides for control of sugarcane aphid.

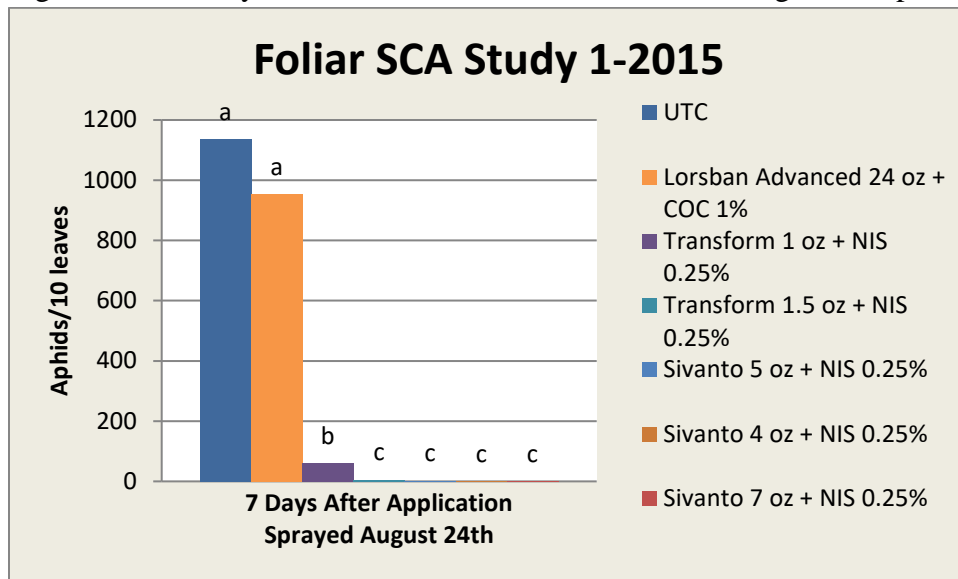


Figure 11. Efficacy of selected insecticides for control of sugarcane aphid.

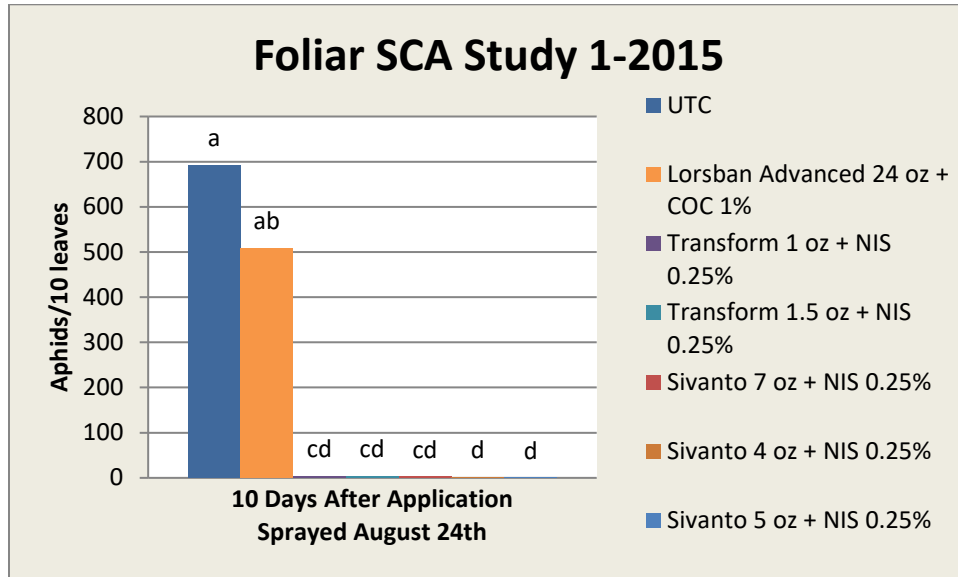


Figure 12. Efficacy of selected insecticides for control of sugarcane aphid.

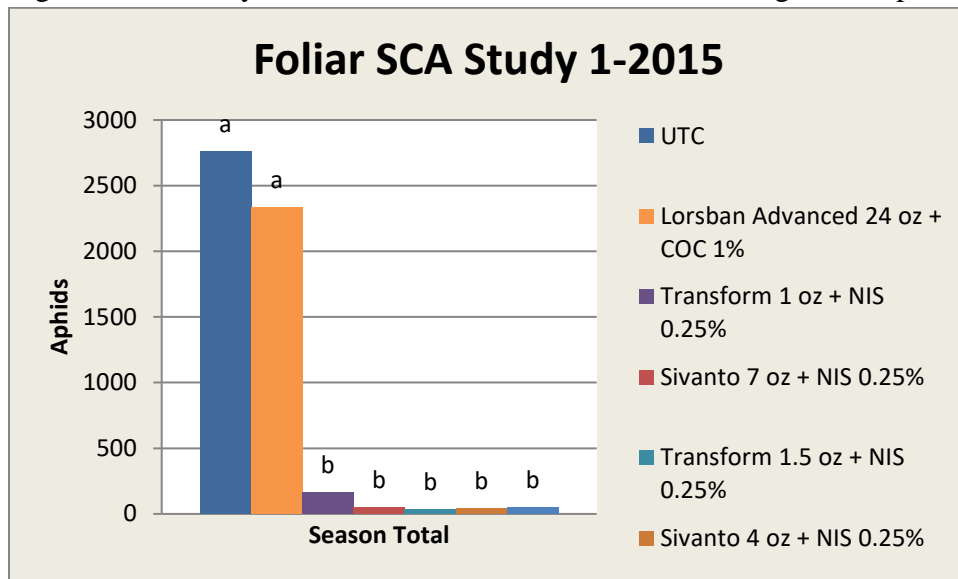
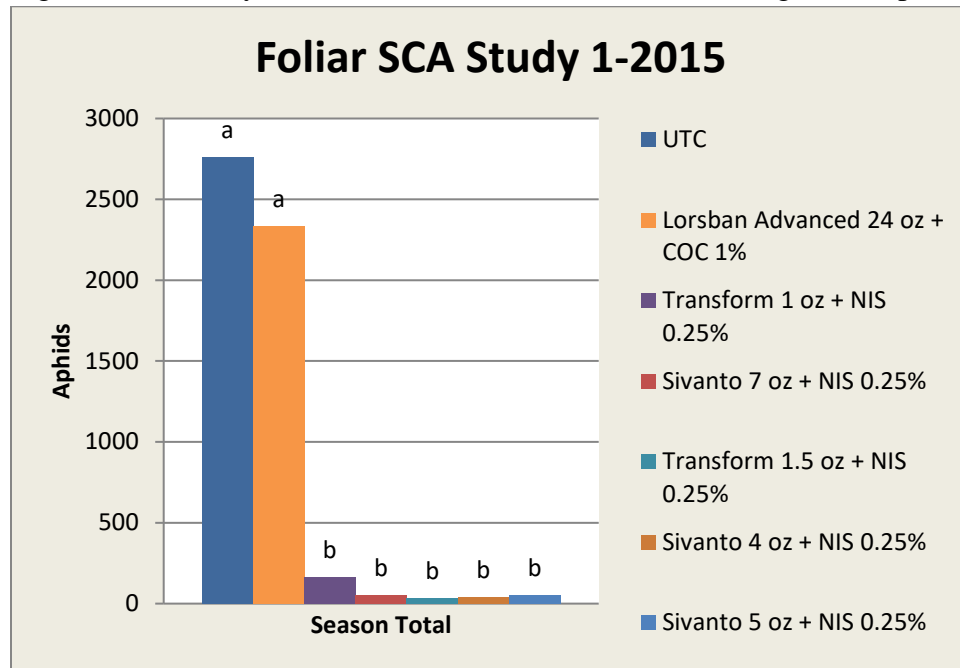


Figure 13. Efficacy of selected insecticides for control of sugarcane aphid.



## SECTION 166.20(a)(6): EXPECTED RESIDUES FOR FOOD USES

### Acute Assessment

Food consumption information from the USDA 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and maximum residues from field trials rather than tolerance-level residue estimates were used. It was assumed that 100% of crops covered by the registration request are treated and maximum residue levels from field trials were used.

Drinking water. Two scenarios were modeled, use of sulfoxaflor on non-aquatic row and orchard crops and use of sulfoxaflor on watercress. For the non-aquatic crop scenario, based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of sulfoxaflor for acute exposures are 26.4 ppb for surface water and 69.2 ppb for ground water. For chronic exposures, EDWCs are 13.5 ppb for surface water and 69.2 ppb for ground water. For chronic exposures for cancer assessments, EDWCs are 9.3 ppb for surface water and 69.2 ppb for ground water. For the watercress scenario, the EDWCs for surface water are 91.3 ppb after one application, 182.5 ppb after two applications and 273.8 ppb after three applications.

Dietary risk estimates using both sets of EDWCs are below levels of concern. The non-aquatic-crop EDWCs are more representative of the expected exposure profile for the majority of the population. Also, water concentration values are adjusted to take into account the source of the

water; the relative amounts of parent sulfoxaflor, X11719474, and X11519540; and the relative liver toxicity of the metabolites as compared to the parent compound.

For acute dietary risk assessment of the general population, the groundwater EDWC is greater than the surface water EDWC and was used in the assessment. The residue profile in groundwater is 60.9 ppb X11719474 and 8.3 ppb X11519540 (totaling 69.2 ppb). Parent sulfoxaflor does not occur in groundwater. The regulatory toxicological endpoint is based on neurotoxicity.

For acute dietary risk assessment of females 13-49, the regulatory endpoint is attributable only to the parent compound; therefore, the surface water EDWC of 9.4 ppb was used for this assessment.

A tolerance of 0.3 ppm for sulfoxaflor on grain sorghum has been established. There is no expectation of residues of sulfoxaflor and its metabolites in animal commodities as a result of the proposed use on sorghum. Thus, animal feeding studies are not needed, and tolerances need not be established for meat, milk, poultry, and eggs.

Drinking water exposures are the driver in the dietary assessment accounting for 100% of the exposures. Exposures through food (sorghum grain and syrup) are zero.

The acute dietary exposure from food and water to sulfoxaflor is 16% of the aPAD for children 1-2 years old and females 13-49 years old, the population groups receiving the greatest exposure.

### **Chronic Assessment**

The same refinements as those used for the acute exposure assessment were used, with two exceptions: (1) average residue levels from crop field trials were used rather than maximum values and (2) average residues from feeding studies, rather than maximum values, were used to derive residue estimates for livestock commodities. It was assumed that 100% of crops are treated and average residue levels from field trials were used.

For chronic dietary risk assessment, the toxicological endpoint is liver effects, for which it is possible to account for the relative toxicities of X11719474 and X11519540 as compared to sulfoxaflor. The groundwater EDWC is greater than the surface water EDWC. The residue profile in groundwater is 60.9 ppb X11719474 and 8.3 ppb X11519540. Adjusting for the relative toxicity results in 18.3 ppb equivalents of X11719474 and 83 ppb X11519540 (totaling 101.3 ppb). The adjusted groundwater EDWC is greater than the surface water EDWC (9.3 ppb) and was used to assess the chronic dietary exposure scenario.

The maximum dietary residue intake via consumption of sorghum commodities would be only a small portion of the RfD (<0.001%) and therefore, should not cause any additional risk to humans via chronic dietary exposure. Consumption of sorghum by sensitive sub-populations such as children and non-nursing infants is essentially zero. Thus, the risk of these subpopulations to chronic dietary exposure to sulfoxaflor used on grain sorghum would be insignificant.

The major contributor to the risk was water (100%). There was no contribution from grain sorghum to the dietary exposure. All other populations under the chronic assessment show risk estimates that are below levels of concern.

Chronic exposure to sulfoxaflor from food and water is 18% of the cPAD for infants, the population group receiving the greatest exposure. There are no residential uses for sulfoxaflor.

Short-term risk. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed, no further assessment of short-term risk is necessary, the chronic dietary risk assessment for evaluating short-term risk for sulfoxaflor is sufficient.

Intermediate-term risk. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no residential exposure and chronic dietary exposure has already been assessed, no further assessment of intermediate-term risk is necessary.

Cumulative effects. Sulfoxaflor does not share a common mechanism of toxicity with any other substances, and does not produce a toxic metabolite produced by other substances. Thus, sulfoxaflor does not have a common mechanism of toxicity with other substances.

Cancer. A nonlinear RfD approach is appropriate for assessing cancer risk to sulfoxaflor. This approach will account for all chronic toxicity, including carcinogenicity that could result from exposure to sulfoxaflor. Chronic dietary risk estimates are below levels of concern; therefore, cancer risk is also below levels of concern.

There is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to sulfoxaflor as used in this emergency exemption request.

*The content in the above Section 166.20(a)(6): “Expected Residues For Food Uses” was prepared by Michael Hare, Ph.D., Texas Department of Agriculture.*

## **SECTION 166.20(a)(7): DISCUSSION OF RISK INFORMATION**

**Human Health Effects- Michael Hare, Ph.D.**

**Ecological Effects- David Villarreal, Ph.D.**

**Environmental Fate- David Villareal, Ph.D.**

### **Human Health**

#### **Toxicological Profile**

Sulfoxaflor is a member of a new class of insecticides, the sulfoximines. It is an activator of the nicotinic acetylcholine receptor (nAChR) in insects and, to a lesser degree, mammals. The nervous system and liver are the target organs, resulting in developmental toxicity and hepatotoxicity.

Developmental toxicity was observed in rats only. Sulfoxaflor produced skeletal abnormalities likely resulting from skeletal muscle contraction due to activation of the skeletal muscle nAChR in utero. Contraction of the diaphragm, also related to skeletal muscle nAChR activation, prevented normal breathing in neonates and increased mortality. The skeletal abnormalities occurred at high doses while decreased neonatal survival occurred at slightly lower levels.

Sulfoxaflor and its major metabolites produced liver weight and enzyme changes, and tumors in sub chronic, chronic and short-term studies. Hepatotoxicity occurred at lower doses in long-term studies compared to short-term studies.

Reproductive effects included an increase in Leydig cell tumors which were not treatment related due to the lack of dose response, the lack of statistical significance for the combined tumors, and the high background rates for this tumor type in F344 rats. The primary effects on male reproductive organs are secondary to the loss of normal testicular function due to the size of the Leydig Cell adenomas. The secondary effects to the male reproductive organs are also not treatment related. It appears that rats are uniquely sensitive to these developmental effects and are unlikely to be relevant to humans.

Clinical indications of neurotoxicity were observed at the highest dose tested in the acute neurotoxicity study in rats. Decreased motor activity was also observed in the mid- and high-dose groups. Since the neurotoxicity was observed only at a very high dose and many of the effects are not consistent with the perturbation of the nicotinic receptor system, it is unlikely that these effects are due to activation of the nAChR.

Tumors have been observed in rat and mouse studies. In rats, there were significant increases in hepatocellular adenomas in the high-dose males. In mice, there were significant increases in hepatocellular adenomas and carcinomas in high dose males. In female mice, there was an increase in carcinomas at the high dose. Liver tumors in mice were treatment-related. Leydig cell tumors were also observed in the high-dose group of male rats, but were not related to treatment. There was also a significant increase in preputial gland tumors in male rats in the high-dose group. Given that the liver tumors are produced by a non-linear mechanism, the Leydig cell tumors were not treatment-related, and the preputial gland tumors only occurred at the high dose in one sex of one species, the evidence of carcinogenicity was weak.

### **Ecological Toxicity**

Sulfoxaflor (N-[methyloxido[1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]-lambda 4-sulfanylidene]) is a new variety of insecticide as a member of the sulfoxamine subclass of neonicotinoid insecticides. It is considered an agonist of the nicotinic acetylcholine receptor and exhibits excitatory responses including tremors, followed by paralysis and mortality in target insects. Sulfoxaflor consists of two diastereomers in a ratio of approximately 50:50 with each diastereomer consisting of two enantiomers. Sulfoxaflor is systemically distributed in plants when applied. The chemical acts through both contact action and ingestion and provides both rapid knockdown (symptoms are typically observed within 1-2 hours of application) and residual control (generally provides from 7 to 21 days of residual control). Incident reports submitted to EPA since approximately 1994 have been tracked via the Incident Data System. Over the 2012 growing season, a Section 18 emergency use was granted for application of sulfoxaflor to cotton

in four states (MS, LA, AR, TN). No incident reports have been received in association with the use of sulfoxaflor in this situation.

Sulfoxaflor is classified as practically non-toxic on an acute exposure basis, with 96-h  $LC_{50}$  values of  $>400$  mg a.i./L for all three freshwater fish species tested (bluegill, rainbow trout, and common carp). Mortality was 5% or less at the highest test treatments in each of these studies. Treatment-related sub lethal effects included discoloration at the highest treatment concentration (100% of fish at 400 mg a.i./L for bluegill) and fish swimming on the bottom (1 fish at 400 mg a.i./L for rainbow trout). No other treatment-related sub lethal effects were reported. For an estuarine/marine sheepshead minnow, sulfoxaflor was also practically non-toxic with an  $LC_{50}$  of 288 mg a.i./L. Sub lethal effects included loss of equilibrium or lying on the bottom of aquaria at 200 and 400 mg a.i./L. The primary degradate of sulfoxaflor is also classified as practically non-toxic to rainbow trout on an acute exposure basis (96-h  $LC_{50}$   $>500$  mg a.i./L).

Adverse effects from chronic exposure to sulfoxaflor were examined with two fish species (fathead minnow and sheepshead minnow) during early life stage toxicity tests. For fathead minnow, the 30-d NOAEC is 5 mg a.i./L based on a 30% reduction in mean fish weight relative to controls at the next highest concentration (LOAEC=10 mg a.i./L). No statistically significant and/or treatment-related effects were reported for hatching success, fry survival and length. For sheepshead minnow, the 30-d NOAEC is 1.3 mg a.i./L based on a statistically significant reduction in mean length (3% relative to controls) at 2.5 mg a.i./L. No statistically significant and/or treatment-related effects were reported for hatching success, fry survival and mean weight.

The acute toxicity of sulfoxaflor was evaluated for one freshwater invertebrate species, the water flea and two saltwater species (mysid shrimp and Eastern oyster). For the water flea, the 48-h  $EC_{50}$  is  $>400$  mg a.i./L, the highest concentration tested. For Eastern oyster, new shell growth was significantly reduced at 120 mg a.i./L (75% reduction relative to control). The 96-h  $EC_{50}$  for shell growth is 93 mg a.i./L. No mortality occurred at any test concentration. Mysid shrimp are the most acutely sensitive invertebrate species tested with sulfoxaflor based on water column only exposures, with a 96-h  $LC_{50}$  of 0.67 mg a.i./L. The primary degradate of sulfoxaflor is also classified as practically non-toxic to the water flea ( $EC_{50}$   $>240$  mg a.i./L).

The chronic effects of sulfoxaflor to the water flea were determined in a semi-static system over a period of 21 days to nominal concentrations of 6.25, 12.5, 25, 50 and 100 mg a.i./L. Adult mortality, reproduction rate (number of young), length of the surviving adults, and days to first brood were used to determine the toxicity endpoints. No treatment-related effects on adult mortality or adult length were observed. The reproduction rate and days to first brood were significantly ( $p<0.05$ ) different in the 100 mg a.i./L test group (40% reduction in mean number of offspring; 35% increase in time to first brood). No significant effects were observed on survival, growth or reproduction at the lower test concentrations. The 21-day NOAEC and LOAEC were determined to be 50 and 100 mg a.i./L, respectively.

The chronic effects of sulfoxaflor to mysid shrimp were determined in a flow-through system over a period of 28 days to nominal concentrations of 0.063, 0.13, 0.25, 0.50 and 1.0 mg a.i./L. Mortality of parent ( $F_0$ ) and first generation ( $F_1$ ), reproduction rate of  $F_0$  (number of young),

length of the surviving F<sub>0</sub> and F<sub>1</sub>, and days to first brood by F<sub>0</sub> were used to determine the toxicity endpoints. Complete F<sub>0</sub> mortality (100%) was observed at the highest test concentration of 1.0 mg a.i./L within 7 days; no treatment-related effects on F<sub>0</sub>/F<sub>1</sub> mortality, F<sub>0</sub> reproduction rate, or F<sub>0</sub>/F<sub>1</sub> length were observed at the lower test concentrations. The 28-day NOAEC and LOAEC were determined to be 0.11 mg and 0.25 mg a.i./L, respectively.

Sulfoxaflor exhibited relatively low toxicity to aquatic non-vascular plants. The most sensitive aquatic nonvascular plant is the freshwater diatom with a 96-h EC<sub>50</sub> of 81.2 mg a.i./L. Similarly, sulfoxaflor was not toxic to the freshwater vascular aquatic plant, *Lemna gibba*, up to the limit amount, as indicated by a 7-d EC<sub>50</sub> for frond count, dry weight and growth rate of >100 mg a.i./L with no significant adverse effects on these endpoints observed at any treatment concentration.

Based on an acute oral LD<sub>50</sub> of 676 mg a.i./kg bw for bobwhite quail, sulfoxaflor is considered slightly toxic to birds on an acute oral exposure basis. On a subacute, dietary exposure basis, sulfoxaflor is classified as practically nontoxic to birds, with 5-d LC<sub>50</sub> values of >5620 mg/kg-diet for mallard ducks and bobwhite quail. The NOAEL from these studies is 5620 mg/kg-diet as no treatment related mortality or sub lethal effects were observed at any treatment. Similarly, the primary degradate is classified as practically nontoxic to birds on an acute oral exposure basis with a LD<sub>50</sub> of >2250 mg a.i./kg bw. In two chronic, avian reproductive toxicity studies, the 20-week NOAELs ranged from 200 mg/kg-diet (mallard, highest concentration tested) to 1000 mg/kg-diet (bobwhite quail, highest concentration tested). No treatment-related adverse effects were observed at any test treatment in these studies.

For bees, sulfoxaflor is classified as very highly toxic with acute oral and contact LD<sub>50</sub> values of 0.05 and 0.13 µg a.i./bee, respectively, for adult honey bees. For larvae, a 7-d oral LD<sub>50</sub> of >0.2 µg a.i./bee was determined (45% mortality occurred at the highest treatment of 0.2 µg a.i./bee). The primary metabolite of sulfoxaflor is practically non-toxic to the honey bee. This lack of toxicity is consistent with the cyano-substituted neonicotinoids where similar cleavage of the cyanide group appears to eliminate their insecticidal activity. The acute oral toxicity of sulfoxaflor to adult bumble bees (*Bombus terrestris*) is similar to the honey bee; whereas its acute contact toxicity is about 20X less toxic for the bumble bee. Sulfoxaflor did not demonstrate substantial residual toxicity to honey bees exposed via treated and aged alfalfa (i.e., mortality was <15% at maximum application rates).

At the application rates used (3-67% of US maximum), the direct effects of sulfoxaflor on adult forager bee mortality, flight activity and the occurrence of behavioral abnormalities is relatively short-lived, lasting 3 days or less. Direct effects are considered those that result directly from interception of spray droplets or dermal contact with foliar residues. The direct effect of sulfoxaflor on these measures at the maximum application rate in the US is presently not known. When compared to control hives, the effect of sulfoxaflor on honey bee colony strength when applied at 3-32% of the US maximum proposed rate was not apparent in most cases. When compared to hives prior to pesticide application, sulfoxaflor applied to cotton foliage up to the maximum rate proposed in the US resulted in no discernible decline in mean colony strength by 17 days after the first application. Longer-term results were not available from this study nor were concurrent controls included. For managed bees, the primary exposure routes of concern include direct contact with spray droplets, dermal contact with foliar residues, and ingestion

through consumption of contaminated pollen, nectar and associated processed food provisions. Exposure of hive bees via contaminated wax is also possible. Exposure of bees through contaminated drinking water is not expected to be nearly as important as exposure through direct contact or pollen and nectar.

In summary, sulfoxaflor is slightly toxic to practically non-toxic to fish and freshwater aquatic invertebrates on an acute exposure basis. It is also practically non-toxic to aquatic plants (vascular and non-vascular). Sulfoxaflor is highly toxic to saltwater invertebrates on an acute exposure basis. The high toxicity of sulfoxaflor to mysid shrimp and benthic aquatic insects relative to the water flea is consistent with the toxicity profile of other insecticides with similar MOAs. For birds and mammals, sulfoxaflor is classified as moderately toxic to practically non-toxic on an acute exposure basis. The threshold for chronic toxicity (NOAEL) to birds is 200 ppm and that for mammals is 100 ppm in the diet. Sulfoxaflor did not exhibit deleterious effects to terrestrial plants at or above its proposed maximum application rates.

For bees, sulfoxaflor is classified as very highly toxic. However, if this insecticide is strictly used as directed on the Section 18 supplemental label, no significant adverse effects are expected to Arkansas wildlife. Of course, standard precautions to avoid drift and runoff to waterways of the state are warranted. As stated on the Section 3 label, risk to managed bees and native pollinators from contact with pesticide spray or residues can be minimized when applications are made before 7 am or after 7 pm or when the temperature is below 55°F at the site of application.

### **Environmental Fate**

Sulfoxaflor is a systemic insecticide which displays translaminar movement when applied to foliage. Movement of sulfoxaflor within the plant follows the direction of water transport within the plant (i.e., xylem mobile) as indicated by phosphor translocation studies in several plants. Sulfoxaflor is characterized by a water solubility ranging from 550 to 1,380 ppm. Sulfoxaflor has a low potential for volatilization from dry and wet surfaces (vapor pressure=  $1.9 \times 10^{-8}$  torr and Henry's Law constant=  $1.2 \times 10^{-11}$  atm m<sup>3</sup> mole<sup>-1</sup>, respectively at 25 °C). Partitioning coefficient of sulfoxaflor from octanol to water ( $K_{ow}$  @ 20 C & pH 7= 6; Log  $K_{ow}$  = 0.802) suggests low potential for bioaccumulation. No fish bio concentration study was provided due to the low  $K_{ow}$ , but sulfoxaflor is not expected to bioaccumulate in aquatic systems. Furthermore, sulfoxaflor is not expected to partition into the sediment due to low  $K_{oc}$  (7-74 mL/g).

Registrants tests indicate that hydrolysis, and both aqueous and soil photolysis are not expected to be important in sulfoxaflor dissipation in the natural environment. In a hydrolysis study, the parent was shown to be stable in acidic/neutral/alkaline sterilized aqueous buffered solutions (pH values of 5, 7 and 9). In addition, parent chemical as well as its major degradate, were shown to degrade relatively slowly by aqueous photolysis in sterile and natural pond water ( $t^{1/2}$ = 261 to >1,000 days). Furthermore, sulfoxaflor was stable to photolysis on soil surfaces. Sulfoxaflor is expected to biodegrade rapidly in aerobic soil (half-lives <1 day). Under aerobic aquatic conditions, biodegradation proceeded at a more moderate rate with half-lives ranging from 37 to 88 days. Under anaerobic soil conditions, the parent compound was metabolized with half-lives of 113 to 120 days while under anaerobic aquatic conditions the chemical was more persistent with half-lives of 103 to 382 days. In contrast to its short-lived parent, the major degradate is expected to be more persistent than its parent in aerobic/anaerobic aquatic systems and some

aerobic soils. In other soils, less persistence is expected due to mineralization to CO<sub>2</sub> or the formation of other minor degradates.

In field studies, sulfoxaflor has shown similar vulnerability to aerobic bio-degradation in nine out of ten terrestrial field dissipation studies on bare-ground/cropped plots (half-lives were <2 days in nine cropped/bare soils in CA, FL, ND, ON and TX and was 8 days in one bare ground soil in TX). The chemical can be characterized by very high to high mobility ( $K_{foc}$  ranged from 11-72 mL g<sup>-1</sup>). Rapid soil degradation is expected to limit chemical amounts that may potentially leach and contaminate ground water. Contamination of groundwater by sulfoxaflor will only be expected when excessive rain occurs within a short period (few days) of multiple applications in vulnerable sandy soils. Contamination of surface water by sulfoxaflor is expected to be mainly related to drift and very little due to run-off. This is because drifted sulfoxaflor that reaches aquatic systems is expected to persist while that reaching the soil system is expected to degrade quickly with slight chance for it to run-off.

When sulfoxaflor is applied foliarly on growing crops it is intercepted by the crop canopy. Data presented above appear to indicate that sulfoxaflor enters the plant and is incorporated in the plant foliage with only limited degradation. It appears that this is the main source of the insecticide sulfoxaflor that would kill sap sucking insects. This is because washed-off sulfoxaflor, that reaches the soil system, is expected to degrade.

In summary, sulfoxaflor has a low potential for volatilization from dry and wet surfaces. This chemical is characterized by relatively higher water solubility. Partitioning coefficient of sulfoxaflor from octanol to water suggests low potential for bioaccumulation in aquatic organisms such as fish. Sulfoxaflor is resistant to hydrolysis and photolysis but transforms quickly in soils. In contrast, sulfoxaflor reaching aquatic systems by drift is expected to degrade rather slowly. Partitioning of sulfoxaflor to air is not expected to be important due to the low vapor pressure and Henry's Law constant for sulfoxaflor. Exposure in surface water results from the drifted parent compound, and only minor amounts are expected to run-off only when rainfall and/or irrigation immediately follow application. The use of this insecticide is not expected to adversely impact Arkansas ecosystems when used according to the Section 18 label. Of course, caution is needed to prevent exposure to water systems because of toxicity issues to aquatic invertebrates. As stated on the Section 3 label, this product should never be applied directly to water, to areas where surface water is present or to intertidal areas below the mean water mark. Also, the label includes the statement "Do not contaminate water when disposing of equipment rinsate."

### **Endangered and Threatened Species in Arkansas**

No impacts are expected on endangered and threatened species by this very limited use of this insecticide as delineated in the Section 18 application. Sulfoxaflor demonstrates a very favorable ecotoxicity and fate profile as stated above and should not directly impact any protected mammal, fish, avian, or plant species. This product does adversely affect insects and aquatic invertebrates, especially bees, but the limited exposure to these species should not negatively affect endangered and threatened species in Arkansas when applications follow the label precautions.

*The above content in Section 166.20(a)(7): Discussion of Risk Information was, for the most part, prepared by Michael Hare, Ph.D. (Human Health Effects), David Villarreal, Ph.D. (Ecological Effects), and David Villarreal, Ph.D. (Environmental Fate), all with the Texas Department of Agriculture. The parts of the above content in this section, with references to Arkansas, were prepared by UA Div of Ag.*

#### **SECTION 166.20(a)(8): COORDINATION WITH OTHER AFFECTED STATE OR FEDERAL AGENCIES**

The following state/federal agencies were notified of the Arkansas State Plant Board's (ASPB) actions to submit an application for a specific exemption to EPA:

- Arkansas Game and Fish Commission
- U.S. Fish and Wildlife Department

Responses from these agencies will be forwarded to EPA immediately if and when received by ASPB.

#### **SECTION 166.20(a)(9): ACKNOWLEDGEMENT BY THE REGISTRANT**

Dow AgroScience has been notified of this agency's intent regarding this application and has offered a letter of support (Attachment 4). They have also provided a copy of the proposed Section 18 label with the use directions for this use (although this use is dependent upon approval by EPA) (Attachment 1).

#### **SECTION 166.20(a)(10): DESCRIPTION OF PROPOSED ENFORCEMENT PROGRAM**

ASPB has state statutory authority to regulate the distribution, storage, sale, use and disposal of pesticides in the state of Arkansas. ASPB will ensure proper use of the product and accurate reporting of the use information.

A final report will be submitted to EPA after the 2014 growing season for which the Section 18 specific exemption is requested. Field enforcement staff at ASPB, as appropriate, will monitor sales of Transform® WG Insecticide, make use observations, and respond to misuse complaints.

#### **SECTION 166.20(a)(11): REPEAT USES**

This is the third time ASPB has applied for this specific exemption.

#### **SECTION 166.20(b)(1): NAME OF THE PEST**

**SECTION 166.20(b)(2): DISCUSSION OF EVENTS OR CIRCUMSTANCES WHICH BROUGHT ABOUT THE EMERGENCY SITUATION**

The events and/or circumstances which brought about the emergency situation are difficult to pinpoint. Obviously the SA shifted its host and moved into sorghum. This shift is not a large move because sugarcane and sorghum belong to the same family of grasses, Poaceae, and the genres of *Saccharum* and *Sorghum* are closely related. The factors which brought about this shift most surely include certain weather conditions (hot, cold, wet, dry) and cropping schemes (acres planted to sugarcane, sorghum, corn, etc.). Also, the lack of efficacious products for control of SA allowed the 2013 SA infestations in sorghum to grow unimpeded. The Texas A&M AgriLife Extension Service publication ENTO-035: 2/14 titled “Sugarcane Aphid: A New Pest of Sorghum” was published in 2013. We used this information and with our supporting data developed our own publication in 2014 (Attachment 6). This publication provides information on the current situation with sugarcane aphid for growers in our state. The rapid movement of this pest through Arkansas with reports of the sugar cane aphid actually causing total crop loss in some areas warrants the need for us to be ready for the pest being a problem for our growers in Arkansas in 2016. We actively work with the Sugarcane Aphid Task Force to effectively communicate and address this pest issue in the southern U.S.

Natural enemies have been observed feeding on the sugarcane aphid, but they apparently had difficulty responding quickly enough to prevent damage. Progress is being made on developing resistant/tolerant sorghum lines, but sufficient quantities of agronomically acceptable cultivars will be years away from commercial use. We plan to have a continued testing program on tolerant/ resistant cultivars in 2016.

**SECTION 166.20(b)(3): DISCUSSION OF ANTICIPATED RISKS TO ENDANGERED OR THREATENED SPECIES, BENEFICIAL ORGANISMS, OR THE ENVIRONMENT REMEDIED BY THE PROPOSED USE**

As previously stated, it is not anticipated that there should be any anticipated risk to endangered or threatened species, beneficial organisms, or the environment if all applications are made in accordance to the section 18 use directions.

- See Attachment B – Endangered and Threatened Species List 2014

**SECTION 166.20(b)(4): DISCUSSION OF SIGNIFICANT ECONOMIC LOSS**

Based on our survey of Arkansas sorghum growers, individual crop damage due to SA infestations (grower estimates) varied widely from 5% to 100% yield loss in many infested fields. Growers were also asked about the estimated reduction in harvest speed due to sugarcane aphid. Comments ranged from a speed reduction of 0 to 50%.

For purposes of the estimate on economic impact we are estimating a 25% yield loss which we consider extremely conservative and an additional insecticide cost with adequate control of \$15/acre, additional cost of application of 1.5 aerial applications and additional cost of a dessicant of \$10/acre and aerial app with that (Figures 14 through 16). On harvest we added an additional cost of 25% reduction in speed due to aphids in combine.

The sugarcane aphid has been found in every county in Arkansas that planted sorghum since its initial expansion in 2014. During the 2014 and 2015 growing seasons, Arkansas producers experienced a 10-100% yield loss in sorghum fields infested with sugarcane aphids. In 2014 trials conducted by the University of Arkansas indicate potential for catastrophic yield loss from sugarcane aphids. (Figures 4-13). This extreme loss in yield results in a significant yield loss for the State of Arkansas. In 2015, Sivanto (flupyradifurone) by Bayer CropScience was labeled and provides very good control and yield protection also, however, supplies have been limited with the expansion of this pest through every sorghum growing region in the U.S. in 2015. Also, there are gaps in the timeline where use of only Sivanto can expose growers to significant yield loss.

Figure 14. Percent increase in yield above the untreated check.

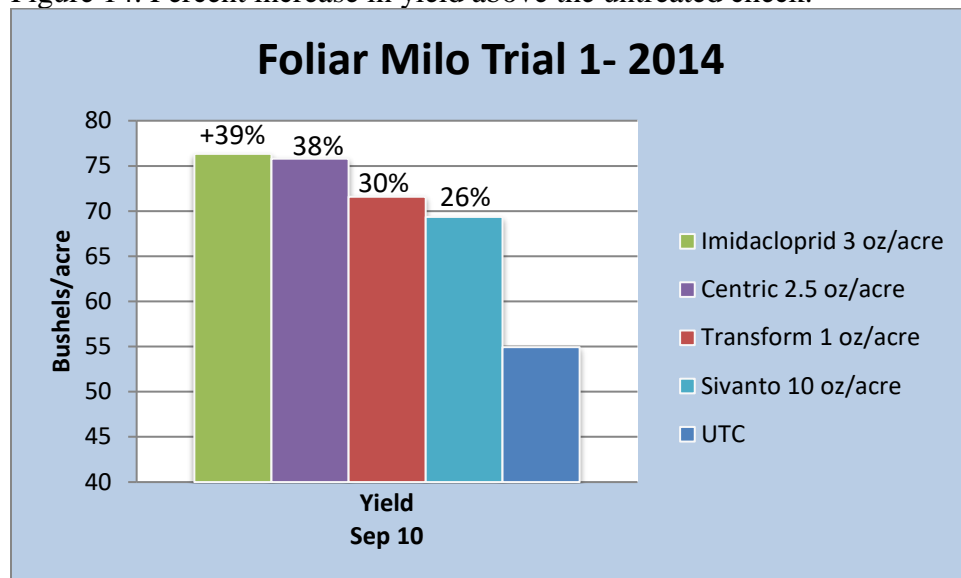


Figure 15. Percent increase in yield above the untreated check.

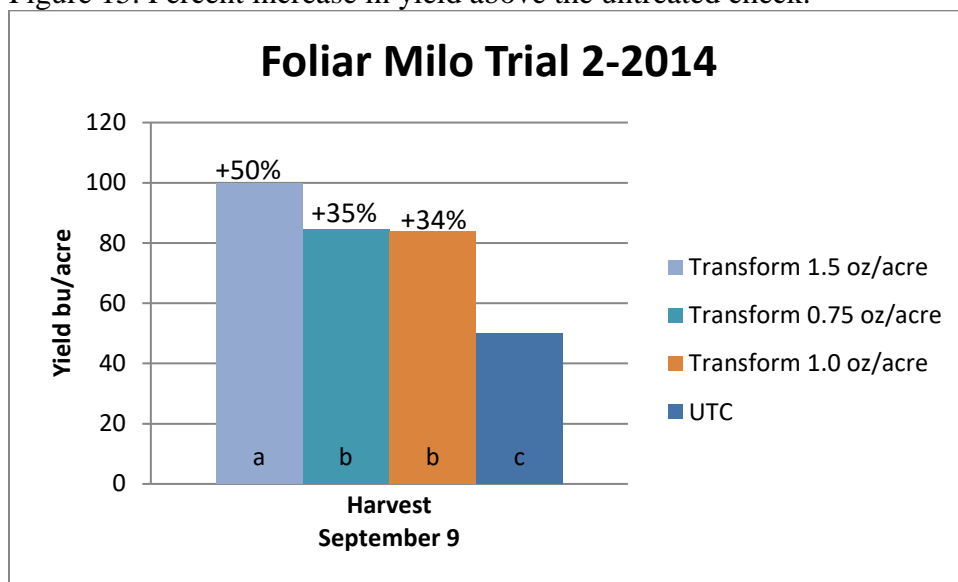
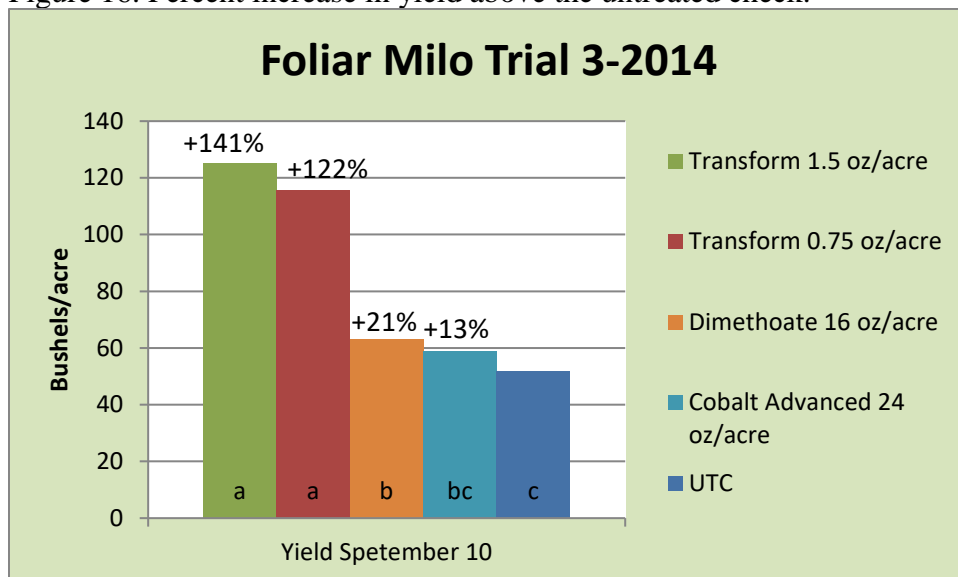


Figure 16. Percent increase in yield above the untreated check.



**SUMMARY:**

The data provided in this document clearly shows yield loss with this pest greatly exceeds 20% in gross revenue. Currently there is only one alternative product on the market and there is the potential for exposure due to gaps in the timeline where the label does not allow sequential application, PHI, or simply there may be more seasonal exposure than the maximum number of seasonal applications allowed. Furthermore it would be not be in the long term interests of our producers or the agriculture industry to treat the entire sorghum producing region of the United States with a single product against a pest known to quickly develop resistance to insecticide chemistry. As we have recently seen pesticide resistance is a critical issue for everyone. There is more than sufficient evidence to justify the use the Transform on and Section 18 exemption for use in grain sorghum in Arkansas. Also, with two years of widespread use in grain sorghum, there has not been a single documented case of acute or chronic effects on honeybees in the immediate or surrounding use areas. We have included letters from two of the largest bee keepers in Arkansas encouraging the use of this product. They know our growers need it and feel it has not been detrimental to them in recent years.